BROOKHAVEN NATIONAL LABORATORY GENERAL CLINICAL RESEARCH CENTER POLICY	GCRC POLICY: IC-03	PAGE 1 OF 2
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SUBJECT: Sterile Supplies Procedures	EFFECTIVE DATE: 7/1/05	
	REVISION HISTORY:2	

1.0 **PURPOSE**

To provide criteria and guidelines for the procedures and use of sterilized supplies in Clinical Studies and to identify techniques to be employed by personnel in the control of possible contamination of these supplies.

2.0 **POLICY**

Personnel shall adhere to the following policies and procedures for proper techniques in the performance of their assigned duties. Compliance requires exercising diligent control against any break in techniques that may result in contamination. Some sterile items will not have an expiration date. These items may be used as long as the integrity of the package is not compromised by becoming wet, torn, damaged or otherwise suspected of being contaminated. The sterile supplies that do have an expiration date are discarded after that date.

3.0 **RESPONSIBILITY/ACCESS**

The responsible Physician shall designate staff as the Sterile Supply Coordinator (SSC) he/she determines to be adequately trained to be responsible for the integrity and availability of sterile supplies for his/her protocol. The Facility Assurance Committee will approve the design of the Responsible Physician. This designated person shall adhere to the following procedures and only those persons designated shall have access to the sterile supply area. GCRC Policy 3.5.

4.0 **PROCEDURES**

4.1 General Procedures

1. SSC SHALL FOLLOW GCRC SATELLITE FACILITY GUIDELINES IC-01.
2. Persons other than authorized personnel are not permitted in the Sterile Supply Area.
3. Scrub gowns, hat and shoe covers shall be worn by all personnel.
4. Handwashing is to be done after handling or touching dirty areas.
5. Carts and bins are to be wiped off not less than weekly or as necessary, with approved germicidal solution.
6. Supplies for delivery outside the Sterile Supply Area are to be covered.
7. Bloodborne Pathogen Exposure Control Plan Guideline IC-06 to be followed.
8. Housekeeping Guidelines IC-12 to be followed.

4.2 Packaging Procedures

All items processed for sterilization will be properly wrapped by the SSC and processed in such a manner as to provide and adequate barrier to microorganisms.

4.3 Transportation of supplies to be sterilized.

4.3.1 After items have been properly wrapped it is the responsibility of the SSC for each research protocol to transport supplies for sterilization to the contractor on a timely basis. GCRC management encourages the various SSC's to coordinate transportation so one SSC goes to the contractor every three months.

4.3.2 The contractor shall provide documentation of the Sterile Supplies procedures used as part of the formal contract (See Attachment 2).

4.3.3 Items transported to and from the outside contractor for sterilization shall be transported in clean plastic tubs with lids. There should be sufficient room in the tub so items are not crushed. Sterile items should be transported from Sterile Supply Area in clean closed containers by the SSC.

4.4 Storage of Sterilized Supplies

4.4.1 The SSC shall assure that sterile supplies are placed in storage bins, drawers or cabinets which are covered and protect the package from damage. Sterile items should be stored at least 8-10 inches from the floor, 18 inches from ceiling and 2 inches from outside walls. Sterile items should be positioned so they are not crushed. Sterile items that are not regularly used should be placed in dust covers. Manufacturer’s cartons that have touched the floor should not be placed into a sterile supply cabinet.

4.4.2 Environmental factors influence sterility: microbial contamination, air movement, temperature and humidity should be considered for storing supplies.

4.4.3 Designated sterile instruments, trays and linen packs shall be placed in dust covers to enhance the barrier efficiency of the original sterile wrapper.

4.5 Use of Sterile Supplies

4.5.1 The SSC shall use stock rotation techniques "First In, First Out", "Left to Right", "Top to Bottom", "Back to Front".

4.5.2 Packages should not be handled more than 3-4 times from sterilizer to subject.

4.5.3 Remember that: Sterility is compromised by dropping, tearing or compression of packages during handling or transport.

4.5.4 All packages must be inspected by the user before the package is opened.

4.5.5 An indefinite shelf label will be placed on each item. A sterilization load indicator will be on each package for recall purposes - this label includes sterilization date and load number.

5.0 **RECALL**

Sterile supplies shall not be used by the SSC until the bacteriological test is returned. If a manufacturer has a recall, remove the affected supply from the shelves. Verify that every single affected item is placed after confirming the following:

1. Product Name
2. Recall number/Lot number
3. Code
4. Manufacturer
5. Reason to recall

If the affected product has been distributed to the various units, staff should be alerted at once by phone and instructed to promptly remove the stock. If an affected item has been used on a subject, the subject's physician should be notified immediately.

6.0 **ATTACHMENT**

Attachment 1

The only official copy of this file is the one online at the Medical Department website under "Clinical Research Center Policy Manual." Before using a printed copy, verify that it is the most current version by checking the document effective date on the website.